TITLE 16 . California Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Department of Consumer Affairs, 400 R Street, Sacramento, CA 95814 at 1:30 p.m. on April 26, 2001.

Written comments must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 9, 2001 or must be received by the Board of Pharmacy at the hearing. Comments may also be faxed to (916) 327-6308 or emailed to Paul_Riches@dca.ca.gov.

The Board of Pharmacy upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 4005 of the Business and Professions Code and Section 2 of Chapter 677, Statutes of 2000, and to implement, interpret or make specific Sections 4125 of said Code, the California Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

Quality Assurance Programs

Section 4125 of the Business and Professions Code requires all pharmacies to establish quality assurance programs designed to reduce medication errors. This section becomes effective January 1, 2002. Section 2 of Chapter 677, Statutes of 2000 requires the board to adopt regulations specifying the requirements for quality assurance programs before September 1, 2001. Section 4005 of the Business and Professions Code permits the board to adopt regulations "as may be necessary for the protection of the public."

The proposed adoption of Title 16, Section 1711 would do the following:

Subdivision (a) requires pharmacies to establish quality assurance programs consistent with this section.

Subdivision (b) defines medication error.

Subdivision (c) requires pharmacies to have written policies and procedures describing the quality assurance program. This subdivision also requires that information regarding the error and corrective actions are communicated to the subject of the error and the healthcare team.

Subdivision (d) requires quality assurance programs to have a process to detect medication errors. It further requires that an investigation of the error commence as soon as possible. Lastly, if the investigation indicates that the error is attributable in whole or in part to the pharmacy or its personnel a quality assurance review must be performed.

Subdivision (e) specifies the minimum elements required in a quality assurance review to include an investigation, documentation of the error, and an essential cause examination.

Subdivision (f) defines "essential cause examination."

Subdivision (g) requires that records relating to the quality assurance review must be retained in the pharmacy.

Subdivision (h) prohibits the discovery of the proceedings or records in a quality assurance review.

Subdivision (i) permits the board to consider compliance with the quality assurance program as a mitigating factor in an investigation.

Subdivision (j) permits pharmacies to contract with third parties to perform quality assurance reviews.

Subdivision (k) specifies that this section becomes operative on January 1, 2002.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: $100,000 in one time cost to the Board of Pharmacy to develop, publish and distribute informational guidelines to pharmacies on quality assurance programs and methods to reduce prescription errors.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy estimates the potential cost impact of the proposed regulations on private persons or entities to be $500 per pharmacy in one-time costs to develop a quality assurance policy. Businesses will assume ongoing costs related to the frequency of medication errors at the individual pharmacy and the cost of completing a quality assurance review for those errors. The public will benefit from these requirements.

Effect on Housing Costs: The board has made an initial determination that the proposed regulation will not effect housing costs.

SMALL BUSINESS DETERMINATION

The Board of Pharmacy has determined that the proposed regulations would affect small businesses.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative which it considered or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons and other information, if any, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814.

AVAILABILITY AND LOCATION OF THE RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the Board of Pharmacy at the address mentioned above.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below.

CONTACT PERSON

Inquiries concerning the proposed administrative action may be addressed to Patricia Harris at the above address or at (916) 445-5014 ext. 4004.

The backup contact person is Paul Riches (916) 445-5014 ext. 4016. The person designated to respond to questions on the substance of the regulatory proposal is Patricia Harris (916) 445-5014 ext. 4004.

WEBSITE ACCESS

Materials regarding this proposal can be found at http://www.pharmacy.ca.gov.